

United States District Court

John Joseph Moakley United States Courthouse

1 Courthouse Way, Suite 6130

Boston, Massachusetts 02210

PATTI B. SARIS
DISTRICT JUDGE

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January 8, 2004

Tommy G. Thompson
Secretary of Health and
Human Services
U.S. Department of Health and
Human Services
Hubert H. Humphrey Building, Rm. 700E
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: In re Pharmaceutical Industry Average Wholesale Price
Litigation, MDL No. 1456, Civil Action No. 01-12257; State
of Montana v. Abbott Labs, Inc. et al., 02-12084; State of
Nevada v. American Home Products Corp., et al., 02-12086;
County of Suffolk v. Abbott Laboratories, Inc., et al., 01-
12257

Dear Secretary Thompson:

I am writing to request that you submit an amicus curiae
brief in the above-referenced litigation.¹

The plaintiffs have brought state-law fraud claims against
pharmaceutical companies alleging that they reported false
information to the Department of Health and Human Services
pursuant to the "Best Prices" rebate program of the federal
Medicaid statute, 42 U.S.C. § 1396r-8 (the "Medicaid Rebate
Statute"). The legal question is whether these claims are
preempted by the Medicaid statute.

¹ As the consolidation of this multi-district litigation
is ongoing, this list of dockets raising the issues discussed
herein is not exclusive.

As background, class plaintiffs in this multi-district litigation allege that the published average wholesale prices ("AWP's") reported by many pharmaceutical manufacturers, which form the basis of prices charged to the plaintiffs by providers, do not reflect the actual average wholesale prices of the drugs. Rather, these published prices are inflated to create a "spread" between the actual wholesale price to each drug provider and the price at which that provider is reimbursed by the end-user, either by Medicare or by a third-party provider. According to the complaints, the providers benefit by keeping the "spread," and each drug manufacturer benefits by giving providers an incentive to use its drug rather than that of a competitor.

Several of the state and county plaintiffs have also alleged that the prices reported to the Department of Health and Human Services pursuant to the "Best Prices" rebate program are fraudulent. They allege that as a result of this fraudulent reporting, the states receive smaller amounts from the drug manufacturers under the "Best Prices" rebate program than their entitlement.

The defendants argue in their motions to dismiss that under the Supreme Court's decision in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 347-53 (2001), the plaintiffs' claims are preempted by the Medicaid Rebate Statute. Defendants argue that under Buckman, the only entity with the ability to enforce violations of the reporting requirements in the statute is the federal government.

Plaintiffs respond that under existing case law, federal preemption is disfavored in the Medicaid context. See Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 74-75 (1st Cir. 2001). The states and counties argue that they have the right and the responsibility to eradicate fraud under the Medicaid statute (specifically under 42 U.S.C. §§ 1396b(q)(3), 1396a(61), and 1396a(25)), which encourages cooperation between the federal government and the states.

Of particular concern to this Court is the issue raised by plaintiffs that the federal government may not have the right to raise claims under the federal False Claims Act to recover the states' "share" of funds, which are paid directly to states by manufacturers. In such a situation, a finding of preemption under the Medicaid Rebate Statute would leave no party in a position to seek a remedy for an alleged fraud.

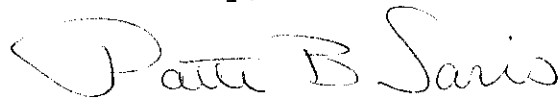
The parties agreed that no prior case has directly addressed

the issue of whether the Medicaid Rebate Statute preempts state-law fraud claims. You are invited to submit an amicus curiae brief on the issues of whether (1) the Medicaid Rebate Statute preempts state law fraud claims based on fraudulent reporting of "Best Prices" to the federal government; and (2) the federal government has the authority to bring suit to recover amounts allegedly owed to the states because of the fraudulent reporting of "Best Prices" to the federal government.

Attached are the briefs on the issue pertaining to the complaints of two of the parties, the states of Montana and Nevada, setting forth in more detail the substance of the dispute. I have also attached my prior opinions in the multi-district litigation.

Please inform me in writing within fifteen (15) days whether you intend to file an amicus brief, and if so, when you will be filing the brief.

Sincerely,

A handwritten signature in cursive script that reads "Patti B. Saris". The signature is written in dark ink and is positioned above the printed name of the signatory.

PATTI B. SARIS
United States District Judge

cc: (without attachments)

Michael J. Sullivan, U.S. Attorney

Jennifer Bowles, Assistant U.S. Attorney

Alex Michael Azar II, General Counsel to U.S. Department of
Health and Human Services